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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,074	08/02/2000	Geoffrey Charles Nicholson	DAV1103.001AUS	9705

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EXAMINER

SAUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/632,074

Applicant(s)

NICHOLSON, GEOFFREY  
CHARLES

Examiner

Christine J. Saoud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) 10, 13-16 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I (claims 1-9 and 17-18, limited to a method of reducing bone resorption by administration of leptin in Paper filed 14 October 2003) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 10, 13-16 and 19 (and claims 1-9 and 17-18, in so far as they are not directed to a method of reducing bone resorption) are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper filed 14 October 2003.

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Australia on August 3, 1999. It is noted, however, that applicant has not filed a certified copy of the Australian application as required by 35 U.S.C. 119(b).

### ***Drawings***

The drawings are objected to because they refer to the subparts of the figure using lower case letters. 37 CFR § 1.84 (U)(1) states that when partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. For

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example, the drawings which are labeled "Figure 4a and 4b" in the instant specification should be renumbered as Figures 4A and 4B (see also Figures 5A-5B). Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 CFR § 1.84 (U)(1), the Brief Description of the Drawings and the rest of the specification must be corrected accordingly.

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. At the time of the instant application, and information disclosure statement had not been received by the PTO.

### ***Claim Objections***

Claims 1-9 are objected to because of the following informalities: they contain non-elected subject matter. The claims should be amended to reflect the elected invention and exclude non-elected subject matter. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9 and 17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Ke et al. (U.S. Pat. No. 6,352,970).

Ke et al. teach a method of augmenting bone mass and preventing bone loss comprising the administration of leptin (see claims beginning at column 18). Ke et al. teach that leptin is useful for treatment of conditions which present with low bone mass, including osteoporosis, bone fractures, osteotomy, etc. (see column 2, lines 30-45). Ke et al. is silent to the effect of leptin on bone resorption, however, as this activity of leptin is inherent to the compound, the method of Ke et al. would inherently inhibit bone resorption via its inherent effects on osteoclasts. The instant claims recite "for a time and under conditions sufficient for the modulation [inhibition] of osteoclastogenesis", however, it would appear that those conditions and times are the same as those taught by Ke et al. for augmenting bone mass and preventing bone loss. The formation of bone is a combination of bone resorption and bone formation, therefore, if the net effect is to prevent bone loss, then resorption would necessarily be inhibited. Therefore, the prior art of Ke et al. anticipates the instant claims.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (American Society for Bone and Mineral Research, 19<sup>th</sup> Annual Meeting, Sep. 10-14, 1997, Cincinnati Ohio).

Liu et al. teach that leptin induces bone formation in ob/ob mice. The data shows that leptin stimulated osteoblasts, possibly inhibited osteoclasts (P value not significant) and overall resulted in an increase in cortical bone formation (see Table). Liu et al. do not teach a method of inhibiting bone resorption by the administration of leptin.

One of ordinary skill in the art at the time of the instant invention would have been motivated to administer leptin to an individual in need to stimulate bone formation, and thereby reduce bone resorption because Liu et al. teach that leptin is effective for stimulating bone formation. One of ordinary skill in the art would have been motivated to administer leptin to an individual with a bone resorption condition, such as osteoporosis, because treatment of such conditions with an agent that stimulates bone formation would be beneficial to the patient. One of ordinary skill in the art would have a reasonable expectation of success in treating an individual, including a human, because the biological effect of leptin in the mouse model would be expected to be predictive of the human condition, absent evidence to the contrary. Therefore, the

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invention as a whole would have been obvious to one of ordinary skill in the art at the time it was made, absent evidence to the contrary.

**Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD  
PRIMARY EXAMINER

*Christine J. Saoud*